City of Huntington v. AmerisouceBergen Drug Corp. et al, 17cv01362
Witness Name: Stacy Harper-Avilla (DEA)
Deposition Date: 2019-04-11
White = Defendants' Counter Designations (w/ Plaintiffs' Objections and Defendants' Responses, if any): 00:28:09
Blue = Plaintiffs' Completeness Designations (w/ Defendants' Objections and Plaintiffs' Responses, if any): 00:14:19
Total Time: 00:42:28

Designations			Objections	Responses
28:13 - 28:22	HARPER-AVILLA, STACY 2019-04-11	1:49		
28:13	Q. Okay. All right. So I want to turn			
28:14	back to your responsibilities as unit chief of			
28:15	the UN reporting and quota section.			
28:16	In that role, what responsibility			
28:17	did you have with respect to establishing			
28:18	quotas for Schedule I and II controlled			
28:19	substances?			
28:20	A. To review the incoming applications,			
28:21	to review documentation, review and assess			
28:22	whether it was scientifically accurate.			
29:20 - 30:17	HARPER-AVILLA, STACY 2019-04-11	1:14		
29:20	Q. In your role as unit chief and now			
29:21	section chief, did you come to have an			
29:22	understanding of the DEA's practices and			
29:23	procedures related to the establishment of			
29:24	quotas?			
29:25	A. Yes.			
30:01	Q. And did that include -- did your			
30:02	understanding include the procedures and			
30:03	practices specifically related to aggregate			
30:04	production quota?			
30:05	A. Yes.			
30:06	Q. And does it also include practices			
30:07	and procedures related to the procurement quota			
30:08	process?			
30:09	A. Yes.			
30:10	Q. Does it also include individual			
30:11	manufacturing quotas?			
30:12	A. Yes.			
30:13	Q. In those positions, did you also			
30:14	gain an understanding of the basis or the			
30:15	reasons why those quotas were set where they			
30:16	were?			
30:17	A. Yes.			
31:03 - 31:07	HARPER-AVILLA, STACY 2019-04-11	0:14		
31:03	Q. Okay. And in any given year during			
31:04	your time at DEA, you understood the reasons			
31:05	the quota was set at the level that it was set			
31:06	at; is that fair?			
31:07	A. Yes.			
32:24 - 33:02				
32:24	Q. Are manufacturers permitted to			
32:25	manufacture any more of a controlled substance			
33:01	than DEA permits through its quota process?			
33:02	A. No.			
34:22 - 35:05				
34:22	Q. Are you familiar with the term			
34:23	"aggregate production quota?"			
34:24	A. Yes.			
34:25	Q. What does that term mean?			
35:01	A. In summary, it is the maximum amount			
35:02	that the United States actually needs for its			
35:03	domestic needs, for legitimate, medical,			
35:04	scientific, research needs, exportation needs			
35:05	and inventory allowances.			

Designations	Objections	Responses
35:13 - 35:24 35:13 Q. Is DEA responsible for determining 35:14 the aggregate production quota? 35:15 A. DEA is the agency that publishes it, 35:16 but we work in concert with other agencies. 35:17 Q. Okay. What other agencies do you 35:18 work with? 35:19 A. FDA. 35:20 Q. Any other agencies? 35:21 A. When necessary, yes. 35:22 Q. What would those other agencies be? 35:23 A. Those within the bounds of DOJ and 35:24 HHS.		
36:10 - 36:14 36:10 Q. You mentioned that at times, you 36:11 consulted with FDA in connection with quota, 36:12 correct? 36:13 A. Yes. 36:14 Q. When did that happen?		
36:17 - 37:05 36:17 THE WITNESS: By statute, by FDA 36:18 statute, they are required to consult with us. 36:19 We are required to have a dialogue however it 36:20 takes place. 36:21 BY MR. O'CONNOR: 36:22 Q. And did DEA comply with its 36:23 obligation to have discussions with FDA? 36:24 A. Yes. 36:25 Q. Did DEA consult with FDA in 37:01 connection with the aggregate production quota 37:02 every year? 37:03 A. I can't guarantee every year, but 37:04 yes, as far as I know, I have seen 37:05 documentation for almost every year.		
41:01 - 41:05 41:01 Q. What is SAMSHA? 41:02 A. I don't remember the full name. 41:03 Q. Fair enough. Do you know generally 41:04 speaking what SAMSHA does? 41:05 A. Substance abuse and mental health.		
41:13 - 41:17 41:13 Q. Did DEA communicate with SAMSHA more 41:14 than once? 41:15 A. Yes. 41:16 Q. Did DEA communicate with SAMSHA on a 41:17 yearly basis regarding quota?		
41:18 - 42:05 41:18 A. Probably, not directly. 41:19 Q. If not directly, how would DEA 41:20 communicate with SAMSHA? 41:21 A. SAMSHA's concerns were usually 41:22 placed in FDA's letter to DEA. 41:23 Q. Okay. Would DEA consider the FDA's 41:24 input when determining the aggregate production 41:25 quota? 42:01 A. Yes. 42:02 Q. And would DEA consider SAMSHA's 42:03 input when determining the aggregate production 42:04 quota? 42:05 A. Yes, when it was there.		
42:06 - 42:21 42:06 Q. Okay. What else would DEA consider		

Designations	Objections	Responses
42:07 when determining the aggregate production 42:08 quota? 42:09 A. DEA would also consider the 42:10 manufacturer's quota application, changes in 42:11 marketplace, manufacturer's changes to their 42:12 processes, export requirements, inventory 42:13 allowances that needed to be done, new 42:14 indication, removal of indications, changes in 42:15 FDA approval. Or changes in -- yeah, changes 42:16 in FDA approval. 42:17 Q. Okay. Between 1995 and 2018, did 42:18 the DEA consider all those factors when setting 42:19 quota? 42:20 A. Yes, that's part of the whole 42:21 statement.		
43:06 - 43:24 43:06 Q. DEA sets aggregate production quotas 43:07 for each individual class of controlled 43:08 substances; is that fair? 43:09 A. DEA sets quota for each class of 43:10 Schedule I or Schedule II controlled substance. 43:11 Q. Fair enough. And what do you mean 43:12 when you say, "class of controlled substance?" 43:13 A. A class is the basic substance. 43:14 Q. Would that include things like 43:15 oxycodone? 43:16 A. Yes. 43:17 Q. Hydrocodone? 43:18 A. Yes. 43:19 Q. Hydromorphone? 43:20 A. Yes. 43:21 Q. Morphine? 43:22 A. Yes. 43:23 Q. Oxymorphone? 43:24 A. Yes.		
43:25 - 44:04 43:25 Q. And when DEA is setting the 44:01 aggregate production quota for each of those 44:02 individual classes, does it consider all those 44:03 factors that you mentioned a moment ago? 44:04 A. Yes.		
48:19 - 48:21 48:19 Q. Sure. And a manufacturer would not 48:20 be allowed to procure more of that molecule 48:21 than the DEA permitted, correct?		
48:22 - 49:01 48:22 A. I think there is a difference 48:23 between would or ability to and should they, 48:24 when the processes work, no they cannot do 48:25 that. If the process does not work, then they 49:01 may.		
54:12 - 54:15 54:12 Q. Were there any years between 1995 54:13 and 2018 when DEA did not consider the actual 54:14 use and need for the material? 54:15 A. It is still --		
54:19 - 54:23 54:19 THE WITNESS: It is still a factor. 54:20 BY MR. O'CONNOR: 54:21 Q. Were there any years in which DEA 54:22 did not consider known diversion when 54:23 determining the aggregate production quota?		

Designations	Objections	Responses
55:01 - 55:06 55:01 THE WITNESS: It's still a factor. 55:02 BY MR. O'CONNOR: 55:03 Q. And were there any years between 55:04 1995 and 2018 in which DEA did not consider 55:05 known abuse when setting aggregate production 55:06 quota?		
55:09 - 55:17 55:09 THE WITNESS: True abuse lay with 55:10 the FDA so it's a factor once again. 55:11 BY MR. O'CONNOR: 55:12 Q. Between 1998 and 2018, did the DEA 55:13 consider changes in the currently accepted 55:14 medical use and treatment with the class when 55:15 considering or setting the aggregate production 55:16 quota? 55:17 A. As set forth by FDA, yes.		
55:18 - 55:20 55:18 Q. Between 1995 and 2018, did DEA 55:19 consider the economic and physical availability 55:20 of raw materials for use in manufacturing --		
55:23 - 56:05 55:23 Q. -- when setting the aggregate 55:24 production quota? 55:25 A. When provided with that information, 56:01 yes. 56:02 Q. And in each year from 1995 to 2018, 56:03 did DEA consider the potential disruptions to 56:04 production when setting the aggregate 56:05 production quota?		
56:07 - 56:09 56:07 THE WITNESS: It's -- it can be 56:08 considered when it's known. Potential is not 56:09 known.		
57:14 - 57:17 57:14 MR. O'CONNOR: Thank you. I'm going 57:15 to mark Exhibit 3. 57:16 (Deposition Exhibit 3 was marked for 57:17 identification.)		
57:18 - 57:24 57:18 BY MR. O'CONNOR: 57:19 Q. Ms. Harper-Avilla, are you familiar 57:20 with this document? 57:21 A. I'm aware of this document. 57:22 Q. Have you seen it before? 57:23 A. I have. 57:24 Q. Would you mind turning to Page 10.		
57:25 - 58:10 57:25 On Page 10, the report reads in 58:01 part: "In establishing APQs for each basic 58:02 class of Schedule I and Schedule II controlled 58:03 substances, DEA considers information from many 58:04 sources, including," and then it lists several 58:05 sources of information. 58:06 First of all, would you agree with 58:07 the statement that in setting aggregate 58:08 production quotas, DEA considers information 58:09 from many sources? 58:10 A. Yes.		
61:16 - 62:01 61:16 Q. But in every year between 2008 and		

Designations		Objections	Responses
61:17	2018, DEA used data either from IMS or IQVIA		
61:18	when setting the annual production quota,		
61:19	correct?		
61:20	A. It was a factor and consideration,		
61:21	yes.		
61:22	Q. And prior to 2008, did DEA consider		
61:23	IMS Health data when setting the aggregate		
61:24	production quota?		
61:25	A. If the contract existed, yes, it		
62:01	did.		
62:07 - 62:10			
62:07	Q. During the years in which DEA used		
62:08	IMS Health data or IQVIA data, did it use that		
62:09	data when setting the aggregate production		
62:10	quota for oxycodone?		
62:12 - 62:19			
62:12	THE WITNESS: The estimate was a		
62:13	factor, a single factor in a multi-factor		
62:14	system.		
62:15	BY MR. O'CONNOR:		
62:16	Q. And during the years in which DEA		
62:17	used IMS Health data or IQVIA data, did it use		
62:18	that data when setting the aggregate production		
62:19	quota for Hydrocodone?		
62:21 - 62:21			
62:21	THE WITNESS: It was a factor in it.		
63:21 - 63:25			
63:21	Q. But for all those classes of		
63:22	controlled substances that are FDA approved,		
63:23	DEA considered IMS Health or IQVIA data when		
63:24	setting the aggregate production quota,		
63:25	correct?		
64:02 - 64:07			
64:02	THE WITNESS: Only for domestic		
64:03	prescription data, yes.		
64:04	BY MR. O'CONNOR:		
64:05	Q. And they considered that in every		
64:06	year from at least 2008 to the present,		
64:07	correct?		
64:09 - 64:11			
64:09	THE WITNESS: Prescription data		
64:10	would be considered as a one point, one single		
64:11	factor in a multi-factored system, yes.		
70:01 - 70:24			
70:01	Q. Okay. The next bullet says:		
70:02	"Estimates of the projected medical, scientific		
70:03	and reserve stock needs provided by FDA's		
70:04	controlled substances staff."		
70:05	Were such estimates considered when		
70:06	determining the aggregate production quota?		
70:07	A. For every year that a letter		
70:08	existed, yes.		
70:09	Q. And between the years 1995 and 2018,		
70:10	are you aware of any years in which FDA did not		
70:11	provide a letter?		
70:12	A. I am not aware.		
70:13	Q. And did DEA consider the estimates		
70:14	provided by FDA when determining the aggregate		
70:15	production quota of each and every opioid		
70:16	product for which it granted quota?		
70:17	A. Yes.		
70:18	Q. How would DEA receive estimates of		

Designations		Objections	Responses
70:19	the projected medical, scientific and reserve		
70:20	stock needs from the FDA?		
70:21	A. In a letter.		
70:22	Q. The same letter, same type of letter		
70:23	you mentioned earlier today?		
70:24	A. It's the exact letter.		
72:07 - 72:11			
72:07	Q. So in addition to the estimates		
72:08	provided by FDA, the DEA also considered the		
72:09	amounts needed to account for yield or loss in		
72:10	production?		
72:11	A. Yes.		
72:13 - 73:01			
72:13	Okay. And is it fair to say that		
72:14	under the regulations regarding quota, DEA was		
72:15	responsible for setting quota at a level that		
72:16	was consistent with the medical, scientific and		
72:17	industrial needs of the United States?		
72:18	A. Yes. And the reserve stock.		
72:19	Q. The last bullet says: "Data on the		
72:20	diversion of controlled substances, such as		
72:21	information from case seizures and national		
72:22	databases of drug evidence."		
72:23	Did the DEA consider that data when		
72:24	establishing aggregate production quota in each		
72:25	and every year between 1995 and 19 -- or in		
73:01	2018?		
73:03 - 73:04			
73:03	THE WITNESS: When the data was		
73:04	available, yes.		
73:23 - 74:11			
73:23	When setting the aggregate		
73:24	production quotas, what data on diversion did		
73:25	the agency use?		
74:01	A. Internal data.		
74:02	Q. What sorts of internal data?		
74:03	A. Known quantifiable seizure data,		
74:04	known quantifiable information received from		
74:05	state and local law enforcement agencies or		
74:06	labs.		
74:07	Q. And to the extent DEA had data on		
74:08	diversion that was quantifiable, did it		
74:09	consider that data in connection with setting		
74:10	the aggregate production quotas for opioids?		
74:11	A. Yes.		
74:07 - 74:18			
74:07	Q. And to the extent DEA had data on		
74:08	diversion that was quantifiable, did it		
74:09	consider that data in connection with setting		
74:10	the aggregate production quotas for opioids?		
74:11	A. Yes.		
74:12	Q. Did it consider that data in setting		
74:13	the aggregate production quota for opioids in		
74:14	each and every year between 1995 and 2018?		
74:15	A. Where it existed, yes.		
74:16	Q. Were there any years during that		
74:17	time period where, to your knowledge, the data		
74:18	did not exist?		
74:21 - 75:10			
74:21	THE WITNESS: There are years where		
74:22	the data was not broken out by controlled		
74:23	substance, so we could not quantify it per		
74:24	controlled substance, and that led to other		

Designations	Objections	Responses
74:25 issues. 75:01 BY MR. O'CONNOR: 75:02 Q. Where the data could not be broken 75:03 out by controlled substance, did the DEA still 75:04 consider that information when setting 75:05 aggregate production quota? 75:06 A. It could not be attributed to a 75:07 specific controlled substance, so no. 75:08 Q. In what years did the data not allow 75:09 the diversion data to be attributed to a 75:10 particular substance?		
75:12 - 75:19 75:12 THE WITNESS: It varied in the years 75:13 based on how the data was submitted to DEA. 75:14 Once again, it's not our internal data. 75:15 BY MR. O'CONNOR: 75:16 Q. And who were you receiving the data 75:17 from? 75:18 A. It would have been state and local 75:19 labs.		
75:20 - 76:05 75:20 Q. Are you aware of any year between 75:21 '95 -- 1995 and 2018 in which diversion data 75:22 regarding oxycodone was not considered when 75:23 setting the oxycodone aggregate production 75:24 quota? 75:25 A. I am not aware when it was not 76:01 considered. 76:02 Q. Are you aware of any year between 76:03 1995 and 2018 in which diversion data regarding 76:04 Hydrocodone was not considered when setting the 76:05 Hydrocodone aggregate production quota?		
76:07 - 76:13 76:07 THE WITNESS: I'm not aware of when 76:08 it was not considered. 76:09 BY MR. O'CONNOR: 76:10 Q. Are you aware of any year between 76:11 1995 and 2018 in which diversion data regarding 76:12 any other opioid product was not considered 76:13 when setting aggregate production quotas?		
76:14 - 76:15 76:14 A. I am not aware, if it's spelled out 76:15 a controlled substance, then we considered it.		
76:16 - 76:20 76:16 Q. So to be clear, was there any year 76:17 between 1995 and 2018 in which DEA did not 76:18 consider diversion data involving any other 76:19 opioid product when setting aggregate 76:20 production quotas?		
76:22 - 76:24 76:22 THE WITNESS: DEA considered 76:23 diversion data when it was a specific 76:24 controlled substance, not a vague term opioid.		
77:01 - 77:05 77:01 Q. Okay. But when DEA had data on 77:02 those specific opioids, it considered that 77:03 diversion data when setting the aggregate 77:04 production quota, correct? 77:05 A. Yes, if we have the data.		
77:06 - 77:10 77:06 Q. And during what years did DEA not		

Designations		Objections	Responses
77:07	have the data?		
77:08	A. I don't recall.		
77:09	Q. Do you recall any year in which DEA		
77:10	did not have that data?		
77:12 - 78:01			
77:12	THE WITNESS: There were -- there		
77:13	was a time frame where the data was not		
77:14	specific to the controlled substance. It was		
77:15	just termed opioid or termed narcotic, and in		
77:16	which case, we could not consider it for the		
77:17	individual scope.		
77:18	BY MR. O'CONNOR:		
77:19	Q. During what years or what time frame		
77:20	did you receive the data that was just termed		
77:21	opioid or narcotic and not broken out by		
77:22	individual molecule?		
77:23	A. There are various times. I don't		
77:24	recall specific ones.		
77:25	Q. So you recall no specific times in		
78:01	which the data wasn't broken out?		
78:06 - 78:12			
78:06	A. The data was whatever it was at the		
78:07	time. If it was broken out by controlled		
78:08	substance, we had it. If it was just termed		
78:09	narcotic, we could not use it for the specific		
78:10	controlled substance, and that could occur at		
78:11	any point in time because we did not input the		
78:12	data, that came from state and local labs.		
80:04 - 81:20			
80:04	Q. Before the aggregate production		
80:05	quota numbers are published in the Federal		
80:06	Register, does someone at the agency have to		
80:07	approve those numbers?		
80:08	A. The final approval of those numbers		
80:09	is by the person who signs the Federal		
80:10	Register.		
80:11	Q. And who is that in the case of		
80:12	aggregate production quotas?		
80:13	A. It would be the administrator or		
80:14	active administrator or the deputy		
80:15	administrator depending on who is in charge at		
80:16	that time.		
80:17	Q. Okay. Before the aggregate		
80:18	production quota numbers go to any of the		
80:19	individuals you just mentioned, are there		
80:20	others at DEA that have to sign off first?		
80:21	A. Yes.		
80:22	Q. Okay. Who are those people that		
80:23	need to sign off first?		
80:24	A. I don't know the exact list of		
80:25	people who sign off, but it would be the head		
81:01	of diversion, as well as whoever is in the		
81:02	chain between that person and the		
81:03	administrator.		
81:04	Q. Okay. When you were --		
81:05	MR. CHANDLER: I'm sorry, I will		
81:06	jump in here. Stacy prepared a list of people		
81:07	in the approval chain going back to at least		
81:08	2011, so I think that would be a good time to		
81:09	work from this, so if you want to testify from		
81:10	that, and we have a copy for you all.		
81:11	MR. O'CONNOR: Thank you.		
81:12	Appreciate that.		
81:13	BY MR. O'CONNOR:		
81:14	Q. And Ms. Harper-Avilla, have you		
81:15	reviewed this document before?		

Designations		Objections	Responses
81:16	A. Yes.		
81:17	Q. And is all the information contained		
81:18	in it accurate?		
81:19	A. Yes.		
81:20	Q. Okay.		
81:21 - 82:16			
81:21	MR. O'CONNOR: I'm going to mark		
81:22	this Exhibit 4.		
81:23	(Deposition Exhibit 4 was marked for		
81:24	identification.)		
81:25	BY MR. O'CONNOR:		
82:01	Q. Just so I understand, this document		
82:02	lists the individuals at DEA who were required		
82:03	to review and approve aggregate production		
82:04	quota before it was published in the Federal		
82:05	Register; is that correct?		
82:06	A. Yes.		
82:07	Q. And while you were unit chief and		
82:08	then section chief, did you also have to		
82:09	approve the quota numbers before they were		
82:10	published in the Federal Register?		
82:11	A. Yes.		
82:12	Q. During any year in which you		
82:13	approved those numbers, did you feel that they		
82:14	did not reflect the legitimate medical,		
82:15	scientific and industrial needs of the United		
82:16	States?		
82:18 - 83:16	HARPER-AVILLA, STACY 2019-04-11 1:29		
82:18	THE WITNESS: No.		
82:19	BY MR. O'CONNOR:		
82:20	Q. After the proposed aggregate		
82:21	production quotas are published in the Federal		
82:22	Register, do members of the public have an		
82:23	opportunity to comment on them?		
82:24	A. Yes.		
82:25	Q. So if someone felt that the		
83:01	aggregate production quotas were too high, for		
83:02	example, would they have an opportunity to		
83:03	submit comments to the DEA reflecting that		
83:04	view?		
83:05	A. Yes.		
83:06	Q. If the DEA received any comments		
83:07	regarding the aggregate production quota, would		
83:08	it take them into account when deciding the		
83:09	final aggregate production quota numbers?		
83:10	A. Can I have the question again.		
83:11	Q. Sure. If the DEA received any		
83:12	comments regarding the aggregate production		
83:13	quota, would it take them into account when		
83:14	deciding the final aggregate production quota		
83:15	numbers?		
83:16	A. Yes.		
83:17 - 84:09			
83:17	Q. Is there a process in place at DEA		
83:18	for determining individual manufacturing		
83:19	quotas?		
83:20	A. Yes.		
83:21	Q. What is that process?		
83:22	A. I don't have it detailed. It's in		
83:23	the C.F.R., but basically, a bulk manufacturer		
83:24	would be required to provide information		
83:25	regarding why they needed that quota.		
84:01	Q. And who considers that request		
84:02	within the agency?		
84:03	A. The UN reporting section does.		
84:04	Q. What factors does DEA take into		

Designations		Objections	Responses
84:05	account when deciding whether to grant or how		
84:06	much to grant with respect to individual		
84:07	manufacturing quota?		
84:08	A. The factors are laid out in the		
84:09	regulation and we consider those factors.		
88:19 - 88:22			
88:19	Q. Sure. If the DEA believed that a		
88:20	manufacturer did not have effective controls		
88:21	against diversion in place, would it grant that		
88:22	manufacturer an individual manufacturing quota?		
88:25 - 89:08			
88:25	THE WITNESS: The DEA has to act on		
89:01	more than belief. As a government entity, it		
89:02	is fact-based, fact-driven.		
89:03	BY MR. O'CONNOR:		
89:04	Q. If the DEA was aware of any facts		
89:05	that a manufacturer was not maintaining		
89:06	effective controls against diversion, would it		
89:07	grant that manufacturer an individual		
89:08	manufacturing quota?		
89:11 - 89:19			
89:11	THE WITNESS: Each manufacturer is		
89:12	allowed due process until the fact is proven		
89:13	with certainty.		
89:14	BY MR. O'CONNOR:		
89:15	Q. So it's your testimony here today,		
89:16	that if you were aware that a manufacturer was		
89:17	not maintaining effective controls against		
89:18	diversion, you would still grant that		
89:19	manufacturer an individual manufacturing quota?		
89:23 - 90:07			
89:23	THE WITNESS: If the DEA had		
89:24	knowledge, it would investigate it, and that's		
89:25	what would occur in between whether a quota was		
90:01	granted or not.		
90:02	BY MR. O'CONNOR:		
90:03	Q. And if that investigation determined		
90:04	that the manufacturer was not maintaining		
90:05	effective controls against diversion, the DEA		
90:06	would not grant it a manufacturing quota,		
90:07	correct?		
90:10 - 90:12			
90:10	THE WITNESS: If the DEA had		
90:11	evidence and the due process was completed, the		
90:12	manufacturer would not be granted quota.		
96:06 - 96:15			
96:06	MR. O'CONNOR: I'm going to mark two		
96:07	documents here as Exhibits 7 and 8.		
96:08	(Deposition Exhibit 7 was marked for		
96:09	identification.)		
96:10	(Deposition Exhibit 8 was marked for		
96:11	identification.)		
96:12	BY MR. O'CONNOR:		
96:13	Q. These are documents that appeared on		
96:14	DEA's website.		
96:15	A. Okay.		
96:24 - 97:09			
96:24	Q. Starting with No. 7, which reflects		
96:25	the aggregate production quota history for		
97:01	selective substances between 2000 and 2010.		
97:02	Do you see that?		
97:03	A. Yes.		

Designations		Objections	Responses
97:04	Q. Do you recognize this chart?		
97:05	A. I recognize the format of the chart,		
97:06	yes.		
97:07	Q. Do you agree that it reflects the		
97:08	aggregate production quota history for the		
97:09	substances listed here on the left?		
97:11 - 98:20			
97:11	THE WITNESS: With the exception of		
97:12	2010, it reflects the aggregate production		
97:13	quota as finalized from 2000 to 2009.		
97:14	BY MR. O'CONNOR:		
97:15	Q. Okay. And with respect to 2010,		
97:16	what does it reflect?		
97:17	A. It would reflect the established.		
97:18	Q. And is it fair to state the		
97:19	established quota might change over the course		
97:20	of the year?		
97:21	A. Correct.		
97:22	Q. Let's look at No. 8, Exhibit 8.		
97:23	A. Yes.		
97:24	Q. And do you agree that this reflects		
97:25	the aggregate production quota history for the		
98:01	substances listed on the left between the years		
98:02	2009 through at least 2018?		
98:03	A. The final aggregate production		
98:04	quota, yes.		
98:05	Q. And I want to direct your attention		
98:06	on Exhibit 7 to the lines that say: "Oxycodone		
98:07	(sale) and oxycodone (CONV)."		
98:08	What does oxycodone (sale) mean?		
98:09	A. That that is the aggregate		
98:10	production quota set for oxycodone that will go		
98:11	to dosage form manufacturers.		
98:12	Q. Okay. And what does oxycodone		
98:13	(CONV) mean?		
98:14	A. So CONV stands for conversion and		
98:15	that is the amount of oxycodone that will be		
98:16	converted to a different substance.		
98:17	Q. And you agree that the numbers		
98:18	listed to the right of oxycodone (sale) reflect		
98:19	the final aggregate production quota for the		
98:20	years listed in the column headings?		
98:23 - 98:24			
98:23	THE WITNESS: For 2000 through 2009,		
98:24	yes.		
99:01 - 99:11			
99:01	Q. Okay. So just to make sure I am		
99:02	reading this correctly, if we look in the		
99:03	column 2008, the number is for oxycodone (sale)		
99:04	70,000.		
99:05	What does that 70,000 represent?		
99:06	A. That 70,000 represents the DEA's		
99:07	estimated final number of the amount of		
99:08	oxycodone for sale that may be required to		
99:09	fulfill legitimate, scientific, medical,		
99:10	research, industrial needs, export as well as		
99:11	inventory requirements.		
99:12 - 99:15			
99:12	Q. Okay. And in coming to that number,		
99:13	did DEA take into account the factors that it		
99:14	was required to consider under the Controlled		
99:15	Substances Act?		
99:17 - 100:03			
99:17	THE WITNESS: Yes.		

Designations		Objections	Responses
99:18	BY MR. O'CONNOR:		
99:19	Q. And in coming to that number, did		
99:20	DEA consider the factors it was required to		
99:21	under the regulation related to aggregate		
99:22	production quota?		
99:23	A. Yes.		
99:24	Q. And with respect to the numbers		
99:25	listed for the other substances here, did the		
100:01	DEA consider all of the factors it was required		
100:02	to consider under the Controlled Substances Act		
100:03	in determining those numbers?		
100:05 - 100:14			
100:05	THE WITNESS: So far as the factors		
100:06	related to that substance, then yes.		
100:07	BY MR. O'CONNOR:		
100:08	Q. Just to address counsel's objection		
100:09	to scope, with respect to all the numbers		
100:10	listed in Exhibits 7 and 8 that are opioids,		
100:11	did the DEA consider all of the factors that it		
100:12	was required to consider by the Controlled		
100:13	Substances Act?		
100:14	A. Where appropriate, yes.		
104:21 - 105:25			
104:21	Q. Would you agree that with respect to		
104:22	aggregate production quota for oxycodone, that		
104:23	DEA considered the factors it was legally		
104:24	required to consider?		
104:25	A. Yes.		
105:01	Q. Okay. With respect to		
105:02	Hydromorphone, in each of the years listed		
105:03	here, do you agree that with respect to		
105:04	aggregate production quota, DEA considered the		
105:05	factors it was legally required to consider?		
105:06	A. Yes.		
105:07	Q. With respect to Hydromorphone --		
105:08	sorry, strike that.		
105:09	With respect to Hydrocodone, in each		
105:10	of the years listed, do you agree that with		
105:11	respect to aggregate production quota, DEA		
105:12	considered the factors it was legally required		
105:13	to consider?		
105:14	A. Yes.		
105:15	Q. With respect to oxymorphone, in		
105:16	setting the aggregate production quota in each		
105:17	of the years listed, do you agree that DEA		
105:18	considered the factors it was legally required		
105:19	to consider?		
105:20	A. Yes.		
105:21	Q. With respect to fentanyl, in setting		
105:22	the aggregate production quota for the years		
105:23	listed here, did DEA consider the factors it		
105:24	was legally required to consider?		
105:25	A. Yes.		
107:08 - 107:11			
107:08	Q. And the numbers that are ultimately		
107:09	published as the aggregate production quota for		
107:10	each of these substances are determined by DEA,		
107:11	correct?		
107:13 - 107:14			
107:13	THE WITNESS: With assistance from		
107:14	other agencies, yes.		
108:14 - 108:17			
108:14	Q. Ms. Harper-Avilla, my name is Chris		
108:15	Eppich. I'm from the law firm of Covington &		

Designations	Objections	Responses
108:16 Burling and I represent McKesson in this 108:17 matter.		
109:01 - 109:21 109:01 Let me -- let me pick up where Mr. 109:02 O'Connor just left off. He asked you a 109:03 question referring to Exhibit 7 and 8. 109:04 He asked you, and I will just read 109:05 it right from the record. He said: "So just 109:06 to make sure I am reading this correctly, if we 109:07 look at the column 2008, the number for 109:08 oxycodone sales 70,000, what does that 70,000 109:09 represent?" 109:10 And your testimony, ma'am, your 109:11 answer: "That 70,000 represents the DEA's 109:12 estimated final number of the amount of 109:13 oxycodone for sale that may be required to 109:14 fulfill legitimate, scientific, medical 109:15 research, industrial needs as well as inventory 109:16 requirements." 109:17 Do you remember providing that 109:18 testimony, ma'am? 109:19 A. Yes. 109:20 Q. And would your answer be the same 109:21 for every year reflected on Exhibit 7 and 8?		
109:23 - 110:06 109:23 THE WITNESS: It would -- it would 109:24 be for legitimate medical needs, scientific 109:25 research, industrial, export as well as 110:01 inventory needs, yes, and then the 110:02 manufacturing losses that are necessary to make 110:03 those final figures. 110:04 BY MR. EPPICH: 110:05 Q. Thank you. And is it also true for 110:06 every opioid that is listed on Exhibit 7 and 8?		
110:08 - 111:11 110:08 THE WITNESS: It would -- it would 110:09 work for those that are -- have FDA-approved 110:10 products. Those that do not, no. 110:11 BY MR. EPPICH: 110:12 Q. And which ones have FDA-approved 110:13 products, ma'am? 110:14 A. That, I can't -- I couldn't cite all 110:15 of those. 110:16 Q. Well, oxycodone is one of them, 110:17 correct? 110:18 A. Correct. 110:19 Q. Hydrocodone? 110:20 A. Yes. 110:21 Q. Hydromorphone? 110:22 A. Yes. 110:23 Q. Morphine? 110:24 A. Yes. 110:25 Q. Fentanyl? 111:01 A. Yes. 111:02 Q. Do any others come to mind after we 111:03 just reviewed five? Oxymorphone, for example? 111:04 A. Correct. 111:05 Q. Oxy -- I will leave it at that. 111:06 Now, Mr. O'Connor asked you several 111:07 questions about the information DEA considers 111:08 in setting the aggregate production quota. 111:09 Do you remember that testimony 111:10 today? 111:11 A. Yes.		
111:12 - 111:18		

Designations		Objections	Responses
111:12	Q. You testified that DEA sets each of		
111:13	these quotas annually, correct?		
111:14	A. Correct.		
111:15	Q. Now, do wholesale manufacturers such		
111:16	as McKesson, Cardinal and AmerisourceBergen		
111:17	provide any information to DEA that is used to		
111:18	set those quotas?		
111:20 - 111:21			
111:20	THE WITNESS: Quotas are not related		
111:21	to distributors, so no.		
112:09 - 112:13			
112:09	Q. DEA does not consult with wholesale		
112:10	distributors, such as McKesson, Cardinal and		
112:11	AmerisourceBergen when DEA sets the quotas for		
112:12	controlled substances, correct?		
112:13	A. Correct.		
112:21 - 112:24			
112:21	Q. Wholesale distributors, such as		
112:22	McKesson, Cardinal, AmerisourceBergen, they do		
112:23	not apply for DEA -- to DEA for quotas, do		
112:24	they?		
113:01 - 113:01			
113:01	THE WITNESS: Correct.		
113:11 - 113:19			
113:11	Q. Now, DEA is required by law to		
113:12	establish aggregate production quotas for		
113:13	certain controlled substances, correct?		
113:14	A. Correct.		
113:15	Q. There are a number of statutes and		
113:16	regulations that govern the process DEA must		
113:17	follow and the considerations DEA must consider		
113:18	in establishing quotas for controlled		
113:19	substances?		
113:21 - 114:16			
113:21	THE WITNESS: Correct.		
113:22	BY MR. EPPICH:		
113:23	Q. And DEA endeavors to comply with		
113:24	these statutes and regulations governing the		
113:25	establishment of quotas for controlled		
114:01	substances, correct?		
114:02	A. Correct.		
114:03	Q. In following these statute and		
114:04	regulations, the aggregated production quota		
114:05	reflects the estimated medical, scientific		
114:06	research and industrial needs of the United		
114:07	States, correct?		
114:08	A. Along with export requirements and		
114:09	inventory requirements and manufacturing yield		
114:10	and losses counted in, yes.		
114:11	Q. The aggregate production quota is		
114:12	the maximum amount of a controlled substance		
114:13	that can be manufactured and distributed in a		
114:14	year, correct?		
114:15	A. It's the maximum amount that can be		
114:16	manufactured within a year.		
124:08 - 124:18			
124:08	Q. I would like to return to Exhibit 4.		
124:09	Exhibit 4 is the document that I		
124:10	understand you or your counsel prepared titled:		
124:11	"APQ Review and Approval."		
124:12	A. Yes.		
124:13	Q. Did you prepare this document,		

Designations	Objections	Responses
124:14 ma'am? 124:15 A. I assisted in it. 124:16 Q. Now, the document starts in 2011, 124:17 correct? 124:18 A. Correct.		
125:20 - 125:23 125:20 Q. Okay. For 2011, we are looking at 125:21 2011 in particular, Mr. Rannazzisi would have 125:22 approved the aggregate production quota amounts 125:23 for each of the classes in 2011, correct?		
125:25 - 126:12 125:25 THE WITNESS: Yes. 126:01 BY MR. EPPICH: 126:02 Q. And the same is true for each year 126:03 that we see Mr. Rannazzisi's name in Exhibit 4; 126:04 is that correct? 126:05 A. Yes. 126:06 Q. Now, Mr. Rannazzisi joined the 126:07 office of diversion control before 2011, 126:08 correct? 126:09 A. Yes. 126:10 Q. And he had a role in his approval or 126:11 authorization of the aggregate production quota 126:12 before 2011?		
126:13 - 126:17 126:13 A. Yes. 126:14 Q. And that would be true for his 126:15 tenure as the deputy assistant administrator 126:16 for the office of diversion control, correct? 126:17 A. Correct.		
219:01 - 219:04 219:01 Q. When you approved those quota 219:02 allocation, you were doing that based on the 219:03 information that you had available to you and 219:04 to the office of the DEA, correct?		
219:06 - 219:06 219:06 THE WITNESS: Yes.		
219:08 - 219:10 219:08 Q. And you did your very best with the 219:09 information that you had to make that 219:10 determination; is that true?		
219:12 - 219:12 219:12 THE WITNESS: Yes.		